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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,971	04/13/2000	Sarah Liljegen	19452A-000700US	7002

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/548,971	Applicant(s) LILJEGREN ET AL.	
	Examiner David H Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003 and 07 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,7,9-18,20-28,30 and 34-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,7 and 9-18 is/are allowed.
- 6) ☒ Claim(s) 20 and 24-41 is/are rejected.
- 7) ☒ Claim(s) 21-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 7 April 2003 has been entered.
2. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 34-40 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification lacks adequate written description support for the limitation "wherein the polynucleotide is at least 65% identical to at least 200 contiguous nucleotides of SEQ ID NO: 1" at claim 34, or "at least 200 contiguous nucleotides of SEQ ID NO: 1" at claim 35. The instant claims encompass new matter not originally presented in the application.

5. Claims 20, 24-28, 30 and 34-40 remain rejected and new claim 41 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 31 December 2002. Applicant's arguments filed 7 April 2003 have been fully considered but they are not persuasive.

Claims 20, 24-28, 30 and 41 are directed to a method of delaying fruit dehiscence in a plant using a polynucleotide encoding an IND1 polypeptide at least 70% identical to SEQ ID NO: 2. Claims 34-40 are directed to an expression cassette comprising a polynucleotide that is at least 65% identical to at least 200 contiguous nucleotides of SEQ ID NO: 1, wherein introduction of said expression cassette into a plant suppresses IND1 expression and results in a plant with delayed fruit dehiscence.

Applicant argues that the teachings of *In re Fiers* are not relevant because it is directed to a situation where no polynucleotide sequences are described (paragraph spanning pages 3-4 of the Remarks). The Examiner concedes the argument and should have cited the decision of *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA

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encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus, which is more pertinent to the instant claims.

Applicant argues that the sequences recited in claim 34 are easy to select and generate (page 4, 2nd and 3rd paragraphs of the Remarks). This argument is not found to be persuasive because SEQ ID NO: 1 describes a 3,856bp polynucleotide, of which 3,656, 200bp fragments are encompassed. In addition, 65% identical to each of those 3,656, 200bp fragments can have up to 70 base pair substitutions of any of the other nucleotides.

6. Claims 20, 24-28, 30 and 34-40 remain rejected and new claim 41 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of delaying fruit dehiscence in a plant comprising transforming a plant with a recombinant expression cassette encoding the IND1 polypeptide of SEQ ID NO: 2 and an expression cassette comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for a method of delaying fruit dehiscence in a plant using a polynucleotide encoding an IND1 polypeptide at least 70% identical to SEQ ID NO: 2 or an expression cassette comprising a polynucleotide that is at least 65% identical to at least 200 contiguous nucleotides of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 31 December 2002, and has been modified in view of Applicant's arguments. Applicant's arguments filed 7 April 2003 have been fully considered but they are not persuasive.

Applicant's arguments as directed to the claimed method in plants other than *Arabidopsis thaliana* is found persuasive and this issue is withdrawn (pages 5-6 of the Remarks).

Applicant argues that the two *Brassica* IND1 sequences described in the previously filed Yanofsky Declaration under 35 USC 1.132, are approximately 75% identical to SEQ ID NO: 2 and that the present claims encompass use of endogenous *Brassica* sequences that are at least 65% identical to SEQ ID NO: 1 to inhibit expression of *Brassica* IND1 sequences (paragraph spanning pages 6-7 of the Remarks). This argument is not found to be persuasive because the Yanofsky Declaration states that two additional gene products from *Brassica napus* are at least 70% identical to SEQ ID NO: 2 and have the same function as the *Arabidopsis* IND1 gene product, not 65% identical thereto, and provides no teachings of amino acid sequences for the two *Brassica* gene products. In addition, Applicant fails to teach how to make and use polynucleotides having the claimed properties in the claimed method and expression cassette. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification

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to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.”. In the instant case, the specification fails to adequately enable the scope of the instant claims.

Applicant argues that the specification specifically teaches that it is desirable to select sequences that are at least similar and preferably highly similar or identical to at least a portion of the endogenous sequence to be inhibited (as directed to the previous rejection of claims 34-40, page 8 of the Remarks). Applicant also argues claim 35 is limited to fragments of SEQ ID NO: 1 and not sequences at least 65% identical (page 9, 2nd paragraph of the Remarks). These arguments are not found to be persuasive because it is Applicant's burden to enable the invention within the scope of the claims and should not require undue trial and error experimentation by one of skill in the art to practice. The arguments are not found to be persuasive because SEQ ID NO: 1 teaches a 3,856bp polynucleotide, of which 3,656, 200bp fragments are encompassed. In addition, 65% identical to each of those 3,656, 200bp fragments can have up to 70 base pair substitutions of any of the other nucleotides. Hence, claims 34-40 encompass an extraordinary amount of trial and error experimentation.

Allowable Subject Matter

7. Claims 5, 7 and 9-18 are allowed.
8. Claims 21-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. Claims 20 and 24-40 remain rejected and new claim 41 is rejected.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
14 November 2003

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